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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,491	11/30/2001	Radmila Mileusnic	3578-120	6361

23973 7590 03/24/2005

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,491

Applicant(s)

MILEUSNIC ET AL

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 10 and 12-35 is/are pending in the application.
- 4a) Of the above claim(s) 12-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 9/29/04. Claims 7 and 10 have been amended. Claims 7, 10 and 12-35 are pending. Applicants have cancelled claims 1-6, 8, 9 and 11. Claims 12-35 are withdrawn from consideration. Therefore, claims 7 and 10 are under consideration.
2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.
4. The Office acknowledges the change in the title.
5. The Office acknowledges the drawings submitted on 11/30/2001.
6. The Office acknowledges the change to the specification.

Claim Rejections - 35 USC § 112, 2nd paragraph withdrawn.

7. Applicants canceling claims 1, 8, 9 and 11 have necessitated the withdrawal of claim rejections under 35 USC § 112, 2nd paragraph.

Claim Rejections - 35 USC § 112, 1st paragraph maintained.

8. The rejection of claims 1-11 (the typographical error omitted claims 9-11 in written description portion of the rejection) under 35 USC § 112, 1st paragraph is maintained for reasons set forth in the Office Action of 3/25/2004. Due to amendments these rejections are only applicable to claims 7 and 10. Applicants arguments filed 9/29/2004 have been fully considered but are not found to be persuasive. Applicants on pages 10 and 11 of the response assert that the Office has admitted that claims as they relate to peptide of

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SEQ ID NO: 4 satisfy the written description requirement. The Office admitted that SEQ ID Nos: 3-11 had adequate written description (pages 4 and 5 of the Office Action).

However, the claims as written encompass polypeptide sequences that comprise SEQ ID NO: 4 and 9, which lack written description in the specification. Therefore, only the peptide sequences corresponding to SEQ ID NO: 4 and 9 but not the full breadth of the claims meet written description provision of 35 USC 112, first paragraph. Thus the rejection of claims 7 and 10 are maintained.

9. The rejection of claims 1-11 under 35 USC § 112, 1st paragraph for failing to comply with enablement requirements is maintained for reasons set forth in the Office Action of 3/25/2004. Due to amendments these rejections are only applicable to claims 7 and 10. Applicants arguments filed 9/29/2004 have been fully considered but are not found to be persuasive. Applicants on page 11 of the response assert that the Office has admitted that claims as they relate to peptide of SEQ ID NO: 4 and 9 satisfy the enablement requirement. The Office found that sequence SMRER and RER represented by SEQ ID Nos: 4 and 9 were enabled (page 7 of the Office Action). However, the claims as written encompass polypeptide sequences that comprise SEQ ID NO: 4 and 9 are not enabled because the quantity of experimentation needed to determine the limitless number of peptide sequences is practically infinite. In addition, the guidance provided in the specification is limited (For, example no activity limitation is provided). Absent further guidance from the specification it would constitute undue experimentation to determine all possible sequences. Therefore, only the peptide sequences corresponding to SEQ ID NO: 4 and 9 but not the full breadth of the claims are commensurate in scope with

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the specification. Thus the rejection of claims 7 and 10 under 35 USC 112, first paragraph are maintained.

Claim Rejections - 35 USC § 102, maintained

10. The rejection of claims 7 and 9-11 as being anticipated by Saitoh et al. (1994, WO 94/09808) is maintained. Applicants' arguments have been fully considered but are not found to be persuasive. It is asserted on page 11 of the response that there is no reference to SMRER (SEQ ID NO: 4) in the reference. However, SEQ ID NO: 17 of Saitoh et al. comprises the SMRER residues describe in the instant invention. In addition, the reference also teaches saline solutions (pharmaceutically acceptable carrier) comprising the peptide (see page 50). Since, claim 7 is drawn a composition comprising amino acids SMRER, the Saitoh reference anticipates the instant invention. Applicants also asserts that claim 10 is not anticipated by Saitoh et al. because according to the Applicants the reference teaches away from any pharmaceutical or therapeutic activity. This is not found to be persuasive because Applicants are using the wrong standard for a 102 rejection. The reference of Saitoh et al teach peptide RER and a pharmaceutically acceptable carrier thus meeting the limitation of claim 10. In addition, the reference also teaches other peptides that comprise amino acids RER. Contrary to Applicants assertion that there is no teaching to support the compositions comprising RER and SMRER having any biological, therapeutic or pharmaceutical activity (response page 12), Saitoh et al. discuss extensively about the biological activity in pages 9-11 of the reference. Therefore, claims 7 and 10 are rejected as being anticipated by Saitoh et al. (1994, WO 94/09808).

11. No claims are allowable.

12. THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

JANET ANDRES
PRIMARY EXAMINER

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 03/05


JANET ANDRES
PRIMARY EXAMINER